REMARKS

The pending Office Action addresses claims 1-6, all of which stand rejected. In conjunction with responding to the Examiner's rejections, Applicants provide the attached §1.132 Declaration of Alastair Hodges dated July 2, 2009. Applicants respectfully request reconsideration and allowance of the present application based on the remarks and the Declaration submitted herewith.

Claim Amendments

The amendments made herein are the same as the amendments submitted by Applicants in the response dated April 6, 2009. The amendments from the response dated April 6, 2009 were not entered by the Examiner and should **not be entered** now; the amendments made herein **should be entered**.

Applicants amend claim 1 to clarify that the electrodes not being co-planar meant that the working electrode and the counter electrode or counter/reference electrode are located on different planes. Support for this amendment can be found throughout the specification, for example at paragraph [0066] and FIG. 12 of the published application. Applicants also amend claim 1 to clarify that the means for applying an electric potential difference, measuring a current, and measuring from cell current the diffusion coefficient of a redox mediator in the cell and independently its concentration is circuitry configured to apply an electric potential difference, measure a current, and determine the diffusion coefficient of a redox mediator in the cell, and independently its concentration, from cell current. Support for this amendment can be found throughout the specification, for example at paragraph [0076] of the published application. Neither of these amendments affect the substance of the claims, and neither is made to overcome any prior art rejections. Rather, both amendments are made for the sake of providing clarity.

Applicants also add new dependent claims 7-11. Claim 7 recites that the circuitry includes a microprocessor. Support for this amendment can be found throughout the specification, for example at paragraph [0077] of the published application. Claim 8 recites that the working and the counter electrode or counter/reference electrode are planar electrodes. Support for this amendment can be found throughout the specification, for example at paragraph [0086] of the published application. Claim 9 recites that the current between the working electrode and the counter electrode or counter/reference electrode achieves a steady-state current. Support for this amendment can also be

found throughout the specification, for example at paragraph [0056] of the published application. Claim 10 recites that the at least one counter electrode or counter/reference electrode is a single electrode. Support for this amendment can be found throughout the specification, for example at paragraph [0050] and FIGS. 1-4 of the published application. Finally, claim 11 recites that the electric potential difference between the working electrode and the counter electrode or counter/reference electrode is an approximately fixed potential. Support for this amendment can likewise be found throughout the specification, for example at paragraphs [0054] and [0055] of the published application.

No new matter is added.

Rejections Pursuant to 35 U.S.C. § 103(a)

Claims 1-4 and 6

The Examiner rejects claims 1-4 and 6 pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,437,999 of Diebold et al. ("Diebold") in view of U.S. Patent No. 5,089,320 of Straus et al. ("Straus"), U.S. Patent No. 5,095,407 of Kanezawa et al. ("Kanezawa"), a June 2001 Imaging Technologies Update from Enthone ("Enthone"), U.S. Patent No. 5,243,516 of White ("White"), and either of two articles from the Journal of Electroanalytical Chemistry, one of which is entitled "Direct Determination of Diffusion Coefficients by Chronoamperometry at Microdisk Electrodes" by Denuault et al. ("Denuault"), and the other of which is entitled "Cyclic Voltammetry for Reversible Redox-Electrode Reaction in Thin Layer Cells with Closely Separated Working and Auxiliary Electrodes of the Same Size" by Daruházi et al. ("Daruházi"). In particular the Examiner argues that the combination of Diebold, Straus, Kanezawa, Enthone, and White teaches the claimed invention except for the "means for measuring from cell current the diffusion coefficient of a redox mediator in the cell and independently its concentration."[1] The Examiner relies on the teachings of Denuault or Daruházi to remedy the deficiencies of the combination of the other references. We respectfully disagree.

The apparatus for determining a concentration of glucose in a blood sample recited in claim 1

[1] This feature is now recited as "circuitry configured to apply an electric potential difference between the working electrode and the counter electrode or counter/reference electrode, measure a current between the working electrode and the counter electrode or counter/reference electrode, and determine the diffusion coefficient of a redox mediator in the cell, and independently its concentration, from cell current."

is an improvement over previous apparatuses because its design results in improved accuracy, reliability, and/or speed. (*See* § 1.132 Declaration of Alastair Hodges dated July 2, 2009 (hereinafter "Hodges Declaration"), ¶ 5.) Prior to Applicants' invention, it was not possible to determine the diffusion coefficient and independently the concentration of a redox mediator of a hollow electrochemical cell in which the working and counter or counter/reference electrodes were separated by a distance of from about 20 microns to about 200 microns. (Hodges Declaration ¶ 5) The Examiner's proposed combination, which includes the electrochemical sensor of Diebold, the meter of White, and the circuitry of either Denuault or Daruházi, fails to render obvious the invention of claim 1 for a number of reasons.

The Meter of White Prohibits Results from Non-Cottrell Currents (e.g., Results as Taught by Denuault and Daruházi) from Being Recognized as Valid

The teachings of Denuault and Daruházi are not compatible with the teachings of Diebold and White. Both Diebold and White are configured in such a manner that the resulting currents between the working and counter electrodes are defined by the Cottrell equation. (Hodges Declaration ¶¶ 8-10.) Thus, the Cottrell equation is relied upon to make determinations of various related values. (*Id.*) Denuault and Daruházi, on the other hand, are configured in such a manner that the resulting currents are defined by equations that are *not* merely Cottrell. (*Id.* ¶ 13.) Thus, equations that are non-Cottrell are relied upon to make determinations of various related values. (*Id.*) Results determined from currents defined by the Cottrell equation are not compatible with results determined from currents defined by non-Cottrell equations. (*Id.* ¶ 8.) This is made explicitly clear by the teachings of White, which are specifically directed to *eliminating* results tied to non-Cottrell behavior *because* of the inaccuracies that result from non-Cottrell behavior in its Cottrell-based meter. (*Id.* ¶¶ 8 and 9.)

A Cottrell current has a behavior that is defined by a particular equation. (*Id.* ¶ 6.) The very nature of the current is such that a steady-state current can never be achieved. (*Id.*) Further, inspection of the Cottrell equation shows that a device that relies on a Cottrell current cannot make a determination of both the diffusion coefficient (D) and independently the concentration of a redox mediator (C_O) from cell current, as required by the claimed invention. (*Id.* ¶ 7.) In the Cottrell equation, D and C_O are dependent upon each other, making it *impossible* to *independently determine* the value of both D and C_O. (*Id.*) Thus, Diebold and White alone cannot result in the present invention.

Recognizing the deficiencies of Diebold and White, the Examiner proposes two separate circuitry options to be used in combination with the electrochemical sensor of Diebold and the meter of White to arrive at the recited invention. (*Id.* ¶ 12.) These two options stem from the teachings found in Denuault and Daruházi. (*Id.*) Both of these options, however, do not exhibit Cottrell-based behavior. (*Id.* ¶ 13.) The systems of Denuault and Daruházi both achieve steady-state currents. (*Id.*) This non-Cottrell behavior is incompatible with the teachings of Diebold and White. (*Id.*)

One reason that neither the teachings of Denuault nor Daruházi can be incorporated into the cell and meter combination of Diebold and White is because the results generated by the circuitry resulting from either Denuault or Daruházi would be considered *invalid* by the meter of White. The meter of White is specifically designed to *eliminate* non-Cottrell behavior. (*Id.* ¶ 8.) Thus, because the results of Denuault and/or Daruházi exhibit non-Cottrell behavior, the results would be classified as invalid by the meter of White. (*Id.* ¶¶ 8, 13, and 21.) Accordingly, the Examiner's proposed combination would result in a device that is unsatisfactory for its intended purpose and thus the combination is improper. (*See* MPEP § 2143.01(V).) Further, the meter of White cannot be adjusted in a manner that would allow it to accept non-Cottrell behavior as valid results because such an adjustment would change the principle of operation of White, which is also improper. (*See* MPEP § 2143.01(VI).) The *entire purpose* of White is to improve biosensing instruments by *eliminating* non-Cottrell behavior results. (Hodges Declaration ¶ 8.)

The Teachings of Denuault Are Not Compatible with Diebold and White

Not only are the teachings of White prohibitive to allowing the Examiner's combination, but the teachings of both Denuault and Daruházi also prevent the Examiner's proposed combination. With specific reference to Denuault, it is taught that microdisk and microsphere electrodes can be used to calculate a diffusion coefficient. (*Id.* ¶¶ 14-19.) More specifically, the geometries of the diffusion volumes of Denuault's electrodes allow for a steady-state current to be achieved, and thus various unknown values can be determined as a result. (*Id.*) Microdisk electrodes, for example, have edge effects that allow for a diffusion coefficient to be calculated. (*Id.* ¶ 15.) The planar electrodes of Diebold, on the other hand, do not have such edge effects, and thus, the techniques taught in Denuault cannot be applied to the electrodes of Diebold. (*Id.* ¶¶ 11 and 14-19.)

While the Examiner has attempted to discredit the techniques of Denuault, alleging that some of the equations are "hypothetical constructs" and that some of the portions of some of the equations

are merely "correction factors," the allegations made by the Examiner are unsupported. The Declaration, on the other hand, clearly illustrates and supports the importance of the diffusion volumes and the terms of the equations related thereto in making independent determinations of various values of the current equations. (*Id.* ¶¶ 14-19.) Every current equation taught by Denuault includes factors related to the geometry of the diffusion volumes. (*Id.*) These factors illustrate that the currents involved achieve a steady-state. (*Id.*) No such factors exist in the teachings of Diebold and White because Diebold and White *cannot* achieve a steady-state current. (*Id.*) Further, these factors from Denuault cannot be incorporated into the cell and meter combination of Diebold and White because Diebold and White are particularly designed *not* to achieve a steady-state current. (*Id.*)

The result of the Examiner's proposed combination would be a device that is unsatisfactory for its intended purpose, and thus no suggestion or motivation can exist to modify Diebold and White in view of Denuault as proposed by the Examiner. (*See* MPEP § 2143.01(V).) Further, there is certainly no reasonable expectation of success that the Examiner's proposed combination would even result in a predictable, functional, and/or desirable device, and as such, the proposed combination is improper. (*See* MPEP § 2143.02.)

Accordingly, the teachings of Denuault are not compatible with Diebold and White, and thus, cannot be combined to result in the present invention.

The Teachings of Daruházi Are Not Compatible with Diebold and White

Daruházi also suffers from a number of deficiencies that prevent it from being able to be combined with the teachings of Diebold and White to arrive at the present invention. Daruházi, like Denuault, also relies on achieving a steady-state current to make its determinations, which at least prevents its results from being recognized as valid by White. (*Id.* ¶¶ 8, 13, 20, and 21.) Daruházi relies on a slow potential sweep process in order to perform its determinations. (*Id.* ¶ 20.) Even if the teachings of Daruházi could be incorporated with the teachings of Diebold and White, a person having ordinary skill in the art would not make such a combination because of the substantial amount of time it would take to carry out a single analysis using the circuitry of Daruházi. (*Id.* ¶ 23.) While the cells and meters of Diebold and White are configured to generate results within 30 seconds, the sweep process of Daruházi takes at least more than four minutes to generate results. (*Id.*) No person having ordinary skill in the art would be motivated to modify Diebold and White to take at least eight

times longer for a single analysis, especially for an apparatus used to measure a patient's blood glucose levels.

Further, the complications that arise from trying to incorporate the electronics of Daruházi into Diebold and White would also prevent a person having ordinary skill in the art from making the Examiner's proposed combination. (*Id.* ¶¶ 24-26.) The significant number of complications that would arise with the electronics in trying to apply the teachings of Daruházi to the devices of Diebold and White would further deter any potential motivation to combine the references as suggested by the Examiner.

Still further, the likely inaccuracies that would occur as a result of trying to incorporate the teachings of Daruházi into Diebold and White serve as even more evidence that a person having ordinary skill in the art would not be motivated to make the Examiner's proposed combination. (*Id.* ¶ 27.)

The result of the Examiner's proposed combination would be a device that is unsatisfactory for its intended purpose, and thus no suggestion or motivation can exist to modify Diebold and White in view of Daruházi as proposed by the Examiner. (*See* MPEP § 2143.01(V).) Further, there is certainly no reasonable expectation of success that the Examiner's proposed combination would even result in a predictable, functional, and/or desirable device, and as such, the proposed combination is improper. (*See* MPEP § 2143.02.)

In view of all of these complications, there is absolutely no reason to combine the slow potential sweep techniques of Daruházi with the devices of Diebold and White to try and create the present invention.

The Thin Layer Electrochemical Cell Teachings of the Present Invention, Diebold, and Daruházi Are Compatible

One issue that the Examiner appears to have trouble rationalizing is the fact that the present invention, Diebold, and Daruházi each disclose thin layer electrochemical cells, and thus, the Examiner believes that each should behave in a similar manner. However, because the term "thin" is a relative term and Diebold does not disclose how far apart its working and counter electrodes are spaced apart, there is no supportable reason why all three necessarily will act similarly. In fact, based on the teachings of Diebold in conjunction with White, it appears that Diebold desires to rely

on a Cottrell current. (Hodges Declaration ¶ 22.) In order to do so, the electrodes must be spaced sufficiently far apart, likely at least greater than 500 microns apart, to achieve this effect. (*Id.*) Thus, there is absolutely nothing contradictory about the configurations of the cells of the present invention, Diebold, and Daruházi that would prevent them from operating exactly how they are disclosed to operate. (*Id.*)

Claim 5

The Examiner rejects claim 5 pursuant to 35 U.S.C. § 103(a) as being obvious over Diebold in view of Straus, Kanezawa, Enthone, White, and Denuault or Daruházi, further in view of U.S. Patent No. 5,126,034 of Carter et al. ("Carter") and U.S. Patent No. 5,399,256 of Bohs et al. ("Bohs").

As noted above, Diebold in view of Straus, Kanezawa, Enthone, White, and Denuault or Daruházi do not teach or even suggest an apparatus that includes both a hollow electrochemical cell and circuitry configured to determine the diffusion coefficient of a redox mediator in the cell, and independently its concentration, from cell current as claimed by Applicants. Carter and Bohs fail to remedy the deficiencies of Diebold, Straus, Kanezawa, Enthone, White, and Denuault or Daruházi. Accordingly, at least because it is dependent upon an allowable base claim (independent claim 1), claim 5 distinguishes over Diebold in view of Straus, Kanezawa, Enthone, White, and Denuault or Daruházi, further in view of Carter and Bohs, and thus represents allowable subject matter.

Claims 7-11

Each of new dependent claims 7-11 are allowable, both because they depend from allowable base claim 1, and further because each includes independently allowable subject matter.

Claim 7 recites that the circuitry includes a microprocessor. None of Diebold, Straus, Kanezawa, Enthone, White, Carter, Bohs, Denuault, and Daruházi teach a microprocessor as part of circuitry configured to determine the diffusion coefficient of a redox mediator in the cell, and independently its concentration, from cell current. Specifically with respect to Denuault and Daruházi, the methods disclosed therein do not teach circuitry or a microprocessor. Accordingly, claim 7 is allowable both because it depends from an allowable base claim, but also because it recites independently allowable subject matter.

Claim 8 recites that the working and counter or counter/reference electrodes of the apparatus are planar electrodes. While the electrodes of Diebold are also planar electrodes, Diebold fails to disclose a way to determine the diffusion coefficient of a redox mediator in the cell, and independently its concentration, from cell current. This is because Diebold uses a current that follows the Cottrell equation, which *cannot* make such an independent determination. As discussed above, Denuault teaches the use of microdisk and microsphere electrodes; microdisk and microsphere electrodes are not planar electrodes. The teachings of Denuault will not work with planar electrodes, and thus just as Denuault cannot be combined with Diebold and White to teach the invention of claim 1, it also cannot be combined with Diebold and White to teach a cell having planar electrodes that can determine the diffusion coefficient of a redox mediator in the cell, and independently its concentration, from cell current. Daruházi also cannot be combined with the teachings of Diebold and White to arrive at the invention of claim 1, and thus also cannot be combined with the teachings of Diebold and White to arrive at the invention of claim 8. Accordingly, claim 8 is allowable both because it depends from an allowable base claim, but also because it recites independently allowable subject matter.

Claim 9 recites that the current between the working electrode and the counter electrode or counter/reference electrode achieves a steady-state current. As discussed above, it is *impossible* for the Cottrell current-based devices and methods of Diebold and White to achieve a steady-state current. Although teachings like Denuault and Daruházi do teach the use of a steady-state current, these teachings cannot be incorporated into the teachings of Diebold and White because they are incompatible. Accordingly, claim 9 is allowable both because it depends from an allowable base claim, but also because it recites independently allowable subject matter.

Claim 10 recites an apparatus that includes only one counter or counter/reference electrode. In order to incorporate the teachings related to a slow potential sweep of Daruházi into Diebold, at least two counter or counter/reference electrodes are needed. This is because a second counter or counter/reference electrode is needed to determine the potential of the working electrode during the sweep. (*See at least* p. 83, last paragraph of Daruházi, which teaches the use of two glassy carbon electrodes and a saturated calomel electrode to serve as the reference electrode.) A person having ordinary skill in the art would recognize that the potential sweep method taught in Daruházi is inoperable with only one counter or counter/reference electrode. Thus, even if the teachings of Daruházi could some how be incorporated into the devices and methods of Diebold and White, the

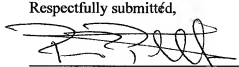
resulting device would include at least two counter or counter/reference electrodes. Accordingly, claim 10 is allowable both because it depends from an allowable base claim, but also because it recites independently allowable subject matter.

Claim 11 recites that the electric potential difference between the working electrode and the counter electrode or counter/reference electrode is an approximately fixed potential. If the teachings of Daruházi were incorporated into the devices and methods of Diebold and White, an approximately fixed potential could not be maintained to determine the diffusion coefficient and concentration of the redox mediator. A potential sweep, like the one taught in Daruházi, requires a variety of potentials be used, and thus an approximately fixed potential cannot be maintained. (*See at least* p. 79, para. 1 and equations 2 and 3.) Thus, even if the teachings of Daruházi could some how be incorporated into the devices and methods of Diebold and White, the resulting device would not include circuitry that provides an electric potential difference that is an approximately fixed potential. Accordingly, claim 11 is allowable both because it depends from an allowable base claim, but also because it recites independently allowable subject matter.

Conclusion

In view of the reasons set forth above, each of the presently pending claims in this application is believed to be in condition for allowance, and reconsideration is respectfully requested. The Examiner is urged to telephone the undersigned Attorney for Applicants in the event that such communication is deemed to expedite prosecution of this matter.

Respectfully submitted,



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